THE STORY OF A SUCCESSFUL BIOTECH (AD)VENTURE: THE DEVELOPMENT OF FLUBLOK

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Biography:
Dr. Manon M.J. Cox, MBA founded NextWaveBio early 2018 following her departure from Protein Sciences Corporation where she led the development of Flublok®, the only FDA approved recombinant influenza vaccine. In August 2017 Sanofi completed the acquisition of Protein Sciences Corporation where she served as President and Chief Executive Officer since April 2010 and Director since 2008. She joined Protein Sciences in 1998 as Director of Business Development and became Chief Operating Officer in 2003. She serves on the Scientific Advisory Boards of Epivax Oncology and Pall BioPharmaceuticals, the Board of Directors of the Netherlands-America Foundation, where she is a member of the Executive Committee and Chairman of its Education Committee, and the Board of Trustees of St. Joseph's University. Before Protein Sciences, she was with Gist-brocades; a large Dutch company specialized in fermentation, where she played a key role in the development of Lipomax® and held various management positions most recently in New Business Development, and before that in Production and Research and Development. Prior to joining Gist-brocades she worked as a Molecular Biologist on the development of a PCR screening test for cervical cancer at the University of Amsterdam. Dr. Cox has received many honours and awards recognizing her stature as a leader in innovation and influenza including receiving a Doctorate in Humane Letters honoris causa from St. Joseph University and the Woman of Innovation award from the Connecticut Technology Council. In 2015 she was elected fellow of the International Society of Vaccines. Dr. Cox holds a Doctorate from the University of Wageningen, received her MBA with distinction from the University of Nijenrode and the University of Rochester, NY and holds a Doctorandus degree in Molecular Biology, Genetics and Biochemistry from the University of Nijmegen, The Netherlands.

Abstract:
I joined Protein Sciences in the late nineties for the people, the products, and the technology. Gale Smith was one of the inventors of the baculovirus technology and Dan Adams one of the founders of the biotech industry. The company was actively involved in vaccine development and the baculovirus expression system was their technology platform. What would be a better place for further learning and driving change in the vaccine industry?

The baculovirus expression system was already an established tool for the production of complex proteins. But we realized that we needed to bring our technology to maturation by taking a product forward through approval by the Food and Drug Administration (FDA) as none of the partners for whom we were developing vaccines using our technology was going to do this for us. An influenza vaccine seemed to be a perfect target as the company had already generated preliminary human clinical data in the mid nineties supporting the hypothesis that a recombinant hemagglutinin (rHA) protein could prevent influenza.

The baculovirus technology was perfectly suited to support the annual updates required for the influenza vaccine as only the baculovirus would need to be modified. Finally, the 1998 H5N1 bird flu outbreak in Hong Kong had clearly revealed the limitations of the egg-based manufacturing process used for the production of influenza vaccines. The National Institutes of Health (NIH) told us that we were the only company in the world that could develop a vaccine "in time" and we met their expectations delivering doses in just eight weeks. However, what seemed to be pretty simple and straightforward project, became a 14-year trajectory that ultimately led to FDA approval of the first recombinant influenza vaccine, named Flublok.

The development of Flublok taught us three important lessons: 1) Use of proven platform technology may lead to new, potentially better products but with the inherent uncertainty it will delay product availability; 2) Allow the regulatory process to focus on safety and evidence of protection in animals, with confirmatory efficacy evidence to be gathered post introduction; and 3) Ensure that adequate funds are available for development.

The speaker will share her experience and the "ups and downs" in the development of Flublok.